



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850**

APR 21 2005

Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K050279
Trade/Device Name: AXS-1 Lite Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: March 24, 2005
Received: March 24, 2005

Dear Dr. Estrin:

This letter corrects our substantially equivalent letter of April 11, 2005 regarding the incorrect trade name listed as Explorer Wheelchair. The correct trade name is listed above.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

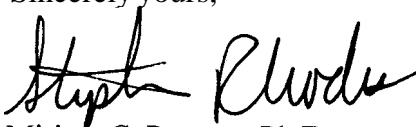
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


for Miriam C. Provost, Ph.D.
Acting Director

Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): K050279

Device Name: AXS-1 Lite Wheelchairs

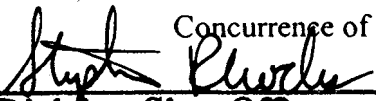
1. Indications for Use: AXS-1 Lite Wheelchairs are indicated for providing mobility to persons limited to a sitting position

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ✓
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

 Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

0010

510(k) Number K050279

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3. SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION

Mr. Patrick Richey
Access Point Medical, L.L.C.
10 Glenville Street
Greenwich, CT 06831

B. ESTABLISHMENT REGISTRATION NUMBER: Pending

C. OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, MD 20854
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Fax: (301) 294-0126

D. DATE OF PREPARATION OF THIS SUMMARY: February 4, 2005

E. PROPRIETARY (TRADE) NAME: Explorer Wheelchair

F. COMMON NAME: Wheelchair

G. CLASSIFICATION NAME: Wheelchair, mechanical

H. REGULATION NUMBER: 21 CFR 890.3850

I. PROPOSED REGULATORY CLASS: Class 1

J. DEVICE PRODUCT CODE: IOR

K. MEDICAL SPECIALTY: Physical Medicine

*10 Glenville Street, Greenwich, Ct 06831 USA
Where well-being and accessibility meet.*

L. DESCRIPTION OF DEVICE

The Access Point Medical **Explorer Wheelchair** is a wheelchair that provides mobility to persons limited to a sitting position. It consists of rigid, mechanical, steel frame and leatherette or nylon upholstery that meets EN102-1: Assessment of the Ignitability of Upholstered Furniture. It has two 24" rear wheels and two 8" front casters for turning and maneuverability. The Access Point Medical Transport Series Transport Chair is intended for use indoors and outdoors, over smooth surfaces (all standard indoor flooring surfaces, concrete, asphalt and packed dirt) that are free of large obstacles and inclines greater than 9 degrees.

M. INDICATIONS FOR USE

The **Explorer Wheelchair** is indicated for providing mobility to persons limited to a sitting position.

N. PREDICATE DEVICE

Jiangsu Inco Medical Equipment Supply Co, EZ-Traveler 3000 Series Wheelchair (K002670).

O. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The **Explorer Wheelchair** and the Jiangsu Inco Medical Equipment Supply Co, EZ-Traveler 3000 Series Wheelchair (K002670) are substantially equivalent products in all areas impacting safety and effectiveness.

P. TECHNOLOGICAL CHARACTERISTICS SUMMARY

Access Point Medical wheelchair production meets the following standards:

- ISO 7171-1 Wheelchair: Determination of static stability
- ISO 7176-3 Wheelchair: Determination of efficiency of brakes
- ISO 7176-8 Wheelchair: Requirements and test methods for static, impact and fatigue strengths
- ISO 7176-11 Wheelchair: Test dummies
- ISO 7176-15 Wheelchair: Requirements for information disclosure, documentation and labeling.
- ISO 7176-16 Wheelchair: Resistance of ignition of upholstered parts – Requirements and test methods
- EN 1021-1 Furniture – Assessment of the Ignitability of Upholstered Furniture

Q. CONCLUSION

Access Point Medical **Explorer Wheelchair** conforms fully to the standards which are noted in Section P as well as applicable 21 CFR references, and meets pinhole FDA requirements, biocompatibility requirements and labeling claims required by these standards. There are no safety/efficiency issues or claims that differ from the predicate device cited.

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